



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-1140]

[Docket No. CDC-2017-0030]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico

(ZIPER Study) to fill gaps in the scientific knowledge base for ZIKV regarding the persistence and transmissibility of ZIKV in body fluids. This information assist ongoing public health response activities, as well as advance the scientific understanding of ZIKV illness and transmission.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0030 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico (ZIPER Study) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC plans to seek a one-year OMB approval to extend information collection covered under OMB Control Number 0920-1140, expiration date 10/31/2017.

The Zika PERSistence (ZIPER) study will help inform the presence and duration of Zika virus (ZIKV) shedding in several body fluids among RT-PCR-positive ZIKV cases from Puerto Rico. It will also provide information regarding the duration of detection of anti-ZIKV Immunoglobulin M (IgM) antibodies and the time for development of Immunoglobulin G (IgG) antibodies among the same population. In addition, this study will determine the prevalence of anti-ZIKV IgM and IgG, and virus shedding in body fluids among household contacts of ZIKV cases.

We propose to investigate the persistence (shedding) of ZIKV in different body fluids and its relation to immune response to provide a basis for development of non-blood-based diagnostic tools, and target and refine public health

interventions to arrest ongoing spread of infection. To do so, we will conduct a prospective cohort study of individuals with reverse transcription-polymerase chain reaction (RT-PCR) positive ZIKV infection and a cross-sectional study of their household contacts. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC.

The study will include baseline and follow-up questionnaires and the collection of the following specimens: blood, saliva, urine from participants of all ages, and semen/vaginal secretions from adults (ages 21 years or older) and legally emancipated minors (support themselves financially, live independent of their parents, are pregnant, or have children). Individuals with RT-PCR positive ZIKV infection will be recruited through the Sentinel Enhanced Dengue Surveillance System (SEDSS) at Saint Luke's Episcopal Hospital in Ponce, Puerto Rico and through passive surveillance in selected municipalities in Puerto Rico. SEDSS was established in 2012 through a cooperative agreement between the hospital in Consortium with the Ponce School of Medicine and Ponce Research Institute from the Ponce Health Sciences University and the CDC (Protocol # 6214). Specimens will be tested for the presence of ZIKV ribonucleic acid (RNA) by RT-PCR at the CDC Dengue Branch Laboratory in San Juan, and positive specimens will be further tested for virus isolation to evaluate infectivity. Each body

fluid will be collected on a weekly basis for 4 weeks and biweekly thereafter until two consecutive negative RT-PCR results are obtained from all specimens. Irrespective of RNA detection, body fluids will also be collected for RT-PCT at 2, 4, and 6 months to investigate intermittent shedding. Analyses of antibody response through titers of IgM and IgG will be performed at baseline and repeated at 2, 4, and 6months. Among symptomatic participants seven milliliters (ml) of blood will be drawn at each study visit split into a tiger top tube (5ml) and a purple top tube (2ml) for a total not to exceed 50 ml during any given 8-week period. At enrollment healthy non-pregnant adults will have 20 ml of blood collected following standard procedures. Two tiger top tubes of 8.5 ml and one 3ml purple top tubes will be collected. These procedures will be repeated at each follow-up visit, see below. RT-PCR-positive participants will be asked to refer up to 5 household members to establish the percentage of household members with detectable and potentially infectious Zika virus RNA in body fluids. Household members who are found to be ZIKV RT-PCR-positive in any body fluid will be invited to participate in the cohort study. A second study visit will be scheduled with household contact at 2 or 4 months, to detect new infections and estimate incidence. Because the original study consent forms do not include this visit, household contacts will be contacted by study staff and

will be consented again using the same consent form.

Since receipt of the initial OMB information collection approval in October 2016, the project has enrolled 295 Zika virus-infected individuals into the Zika virus Persistence study, which are 55 individuals below the target enrollment of 350 individuals. Nonetheless, preliminary findings have been published in New England Journal of Medicine, where we also expect that the final report that includes the full sample size will be published.

This is a request to continue information collection with minor modifications. Modifications have been made to reflect the developing nature of the science surrounding Zika virus infection and potential outcomes associated with infection, as well as additional questions that were best answered by taking advantage of the existing study platform. Specifically, CDC proposes the addition of two components to the collection of data under this study, one of which has already begun:

1. A follow-up household visit has been added to determine how many household members of Zika virus-infected participants become infected during the 4 months following initial screening. For any household members that had no evidence of Zika virus infection at the initial visit, the same questionnaires used at the initial household visit will again be completed ~4 months later. Such information will provide

additional information regarding the incidence of Zika virus infections among households with a Zika-positive household member.

2. Additionally, CDC proposes following up with men with Zika virus-positive semen specimens to better understand the effect of Zika virus infection on sperm. To do this, 8-14 semen ejaculates from 10-20 men participating in the ZIPER study will be used to determine the presence and/or detection of the Zika virus in different fractions of the semen ejaculate (i.e., seminal plasma, cellular debris, including White Blood Cells [WBCs] and spermatozoa). CDC's Institutional Review Board (IRB) has approved this modification, but information collection has not begun.

There is no cost to respondents other than the time to participate.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 USC 241).

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Public health personnel	Shedding Questionnaire (Symptomatics)	55	8	10/60	74

	Shedding Questionnaire (Cross- Sectional Asymptomatics)	100	1	10/60	17
	Questionnaire for men semen sub-study	30	1	20/60	10
General public	Shedding Eligibility Form	160	1	2/60	6
	Contact Information Form	32	1	2/60	1
Total					108

Leroy A. Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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